



Contact GEX for a MS Word copy of this document. This document was formerly published as *GEX Doc. No. 100-258 Measuring GEX B3 Dosimeters*.

1 - Purpose

To describe the process for post-irradiation handling and measurement for GEX B3 dosimeters.

2 - Scope

This procedure applies to GEX B3 dosimeters used for validation and routine monitoring of the irradiation process.

[TO BE REMOVED BY USER Caveat emptor - This procedure applies specifically to the GEX DoseControl dosimetry system software but users of other dosimetry software or systems can modify this procedure to suit their specific system.]

[Note: Before implementing this procedure, add pictures and modify the workflow according to site specifics.]

3 - General Information

About B3 Dosimeters

GEX B3 dosimeters are radiochromic film dosimeters with a nominal thickness of 18 microns. They are used for absorbed dose measurements in radiation processing. When irradiated, a chemical reaction occurs within the film causing a change in the visible light spectrum which is quantifiable and directly related to the absorbed dose of ionizing radiation the dosimeter receives. For detailed information refer to *GEX Doc# 100-101, GEX B3 Dosimeters – Product Specification and Usage* - download from the GEX document library [Document Library - GEX Document Library](#).

Each B3 dosimeter is framed by a laminated paper overlay which is printed with unique identification information consisting of a batch ID of two alpha characters and a 7-digit numerical serial number comprising the identification code in the electronic form "XX_0000000". The two parts of the code are separated by a single or double underscore ('_'). GEX manufacturing processes ensures dosimeter IDs are never replicated or repeated, so the identification code is unique for each individual dosimeter.

B3 dosimeters come in various styles of packaging, but they require the same general handling and follow the same measurement process. Specifically, the following general rules apply:

- The user should not touch the film with bare skin of fingers which may contaminate the film's surface and affect the optical measurement of the film. The dosimeters must be handled in a manner to prevent touching the film such as the use of forceps, powder free gloves, and handling the films by the paper 'frames', when applicable.
- The dosimeter is measured at a fixed wavelength of 552 nm \pm 2 nm using a spectrophotometer with a spectral bandwidth not less than 4 nm.





- B3 dosimeters must be heat-treated after irradiation before the dosimeter can be measured. The dosimeter is incubated after irradiation to catalyze the chemical reaction in a process called 'heat-treatment'. After heat-treatment, the dosimeter absorbance is stable making measurements repeatable over a period of many days.

Requirements for Reporting Dosimeter Measurement Data

Specific information should be associated with (by reference to another documented record) or documented and reported with the dosimeter measurements in the dosimetry report. Users may choose to associate a process ID number and reference that on the dosimetry report. Other times, users prefer to have specific information documented explicitly on the dosimetry report. No matter the choice, for dosimeter measurement information to be useful, the user must associate specific information to each dosimeter, such as (the examples are not comprehensive):

- The position or location of the dosimeter on the product or in the process,
- The date/time a process occurred,
- The process specification and any relevant process parameters.

For example, 'reference monitoring location' is a term used to describe a standard position used for routinely monitoring the irradiation process that is defined in the user's procedures. Location/Position information can be written onto the dosimeter packaging, or the user can assign a specific dosimeter ID to a location in advance or use any electronic means to record and verify dosimeter positions.

The dosimetry system generates records of all the internally static or created information, so the user does not need to plan to record these separately. For example, the name of the person that measured the dosimeter, the instrument ID used, the date and time of measurement, etc.

4 - Prerequisites

4.1 ALTERNATIVELY, reference *Implementation Guide for the DoseControl Dosimetry System*.

4.2 The spectrophotometer and associated holder system have been installed in accordance with GEX's instructions given in the documents below for the model of spectrophotometer being used:

Spectrophotometer Model	GEX Document Number
Thermo Scientific Evolution	100-156
Thermo GENESYS 30	100-167

Download spectrophotometer and dosimeter holder apparatus product information from the GEX document library [Document Library](#) - GEX Document Library. Search by product name or number.





4.3 The spectrophotometer is calibrated traceable to a national standard, and a sticker is placed on the instrument detailing the date of the last calibration and the due date of the next (or in accordance with the user’s site procedure for labeling of calibrated equipment).

Procedure Name	GEX Document Number
GENESYS 30 Performance Verification Procedure	100-270
Evolution Performance Verification Procedure	100-271

Download spectrophotometer performance verification procedures and forms from the GEX document library [Document Library - GEX Document Library](#).

4.4 The DoseControl software has been installed and configured, and the operation of the spectrophotometer by the software has been qualified. See DoseControl User Guide.

4.5 The user has reviewed and demonstrated basic proficiency in using the hardware and software in accordance with GEX’s user guides and instructions.

4.6 Irradiated dosimeters to be measured have been heat treated in accordance with local procedure. Refer to *Post Irradiation Heat Treatment of GEX B3 Dosimeter Products*.

5 - Procedure

5.1 Spectrophotometer Power On / Waiting Period

5.1.1 Close the spectrophotometer lid and turn on the power. The instrument will execute a power-on, self-test sequence.

5.1.2 Warm up the spectrophotometer in accordance with the instructions in the relevant user guide or instruction document for the model being used.

5.1.2.1 *[Copy the procedure for the instrument being used from the referenced document and insert here so the procedure has explicit instructions]*

5.1.3 When the spectrophotometer is on any wait period before warm-up is complete, open the GEX DoseControl Dosimetry Software on the PC attached to the spectrophotometer. For complete instructions see - DoseControl Software User Guide - How to Use DoseControl

5.1.4 Keep the spectrophotometer lid closed during powering on and warm up.



**Sections 5.2 to 5.9**

These sections are a general process overview. For complete instructions for how to measure dosimeters see - DoseControl Software User Guide - How to Use DoseControl

5.2 Open/Create Dosimetry Report in DoseControl

5.2.1 Create a dosimetry report in the software using the 'New Report' button or open an existing report by selecting the report ID in the list on the 'Search Reports' screen.

5.2.2 Based on the selection of 'Dosimeter Batch' and irradiation pathway, the software automatically chooses the one and only available calibration for the spectrophotometer ID that is connected to the PC.

Note: The software only allows one calibration to be active for any combination of dosimeter batch, instrument ID (reader), and pathway.

5.2.3 If no calibration exists or if the calibration dates for dosimeter response function or the calibration dates for the spectrophotometer are out of range, the software will present an error telling the user that it cannot proceed. Refer the Appendix on troubleshooting in DoseControl User Guide. or contact your DoseControl Application Administrator at your facility.

5.3 Preparing for Measurement / Zeroing

5.3.1 DoseControl software will open the measurement screen for the report.

5.3.2 Insert the correct holder into the spectrophotometer baseplate for the dosimeter being used. (GEX B3 or Cuvette dosimeter holder).

5.3.2.1 If you are using the hinged dosimeter holder in the Cuvette, you should zero with an empty hinged-holder placed in the Cuvette.

5.3.2.2 If you are performing a performance verification using the Cuvette and the Thermo Spectronic Standard, you should zero with an empty Cuvette with the spectrophotometer LID CLOSED. This will prevent stray light from entering the Cuvette.

5.3.3 The lid of the spectrophotometer can remain open when using the spectrophotometer for routine dosimeter measurements (e.g., zeroing and measurement). This includes dosimeter measurements using the GEX B3 holder and the hinged-holder in the Cuvette holder

5.3.4 Follow the on-screen instructions to zero the spectrophotometer with the correct dosimeter holder.

5.3.4.1 Click the 'OK' button and DoseControl will execute the zeroing function of the spectrophotometer.





5.4 Dosimeter Measurements

5.4.1 On the measurement screen, the software requires the user to enter a “dosimeter ID”. The dosimeter ID must be unique, and cannot be duplicated in the software. There are several methods to enter a dosimeter ID:

5.4.1.1 Use an integrated barcode scanner (installed inside the sample compartment of the spectrophotometer). When the user clicks the “Measure” button, the dosimeter ID is automatically captured by the software at the time of measurement.

5.4.1.2 Not using an integrated (internal) barcode scanner, a dosimeter ID must be entered in the software before a measurement can be taken. There are three options:

- Manually enter the dosimeter ID using the keyboard,
- Use a desktop/handheld barcode scanner to scan the dosimeter’s barcode,
- In DoseControl, configure the dosimeter batch calibration to “auto-generate” ID number. The software will automatically create a unique, random dosimeter ID when a dosimeter is measured. (Note: The auto-generated ID will not match the dosimeter’s printed unique ID/barcode. The user will need to keep the dosimeter order, placement, location information for each dosimeter).

5.4.2 Insert the dosimeter into the holder inside the spectrophotometer sample compartment.

5.4.3 For DoseStix style dosimeters, place the dosimeter directly into the DoseStix holder inside the spectrophotometer.

5.4.4 For WINdose style dosimeters, place the dosimeter into the hinged holder and then place the hinged holder into the WINdose cuvette inside the spectrophotometer.

5.4.5 Press the ‘Measure’ button on the measurement screen and the value is measured and transferred from the spectrophotometer to the software.

5.4.6 Enter any associated ‘tote’ or ‘position’ information for the dosimeter that was just measured. Press “Save” to save the tote and position information associated with that dosimeter measurement.

Note: Despite the on-screen labels, the Tote and Position fields can be used to enter a variety of information. These fields may be auto-filled if using the data integration feature of DoseControl (Enterprise License only).

5.4.7 Repeat the steps above (5.4.1-5.4.6) and measure all dosimeters for a single report or session.

5.5 Rereading Dosimeters

5.5.1 Reread any dosimeter, as applicable. To reread a dosimeter, press the ‘Reread’ button on the measurement screen. The “Reread” button is located below the “Measure” button. The reread value replaces the original value on the screen and in the output report.





5.5.2 In all cases, the original measurement is never overwritten but the system will update the value on screen if the reread is accepted according to the rules that are configured for "Rereads". Therefore, previous values for any Dosimeter ID can be reviewed as part of the system's Audit Trail.

5.5.3 The software has three types of reread workflows, configured by the DoseControl Admin, described below:

5.5.3.1 Default Rereads – Without any configuration, this is how the system works off-the-shelf. Users reread at-will.

5.5.3.2 Simple Rereads – Allows configuration of some variables to limit workflow or reread allowance (e.g. may only reread a dosimeter one time). Replaces the existing value if the workflow allows the reread button to be active.

5.5.3.3 Statistical Rereads – Allows configuration of some variables to limit workflow or reread allowance (e.g. may only reread a dosimeter once per session). Forces the user to measure for repeatability by taking 3 successive readings of the same dosimeter and calculates the average. The average replaces the existing value if the workflow allows the reread button to be active and passes a check of variation between the three readings.

5.5.4 The following reread rules apply to this site:

5.5.4.1 *[Insert list of rules, if any, for this site]*

5.6 Review of Work

5.6.1 When all dosimeter measurements are complete, select the 'Summary Screen' button.

5.6.2 On the summary screen are sections of the data that can be expanded or minimized. Expand them all and review all the data for completeness and accuracy of manually entered data for all sections.

5.6.3 Enter any notes for this report into the 'Notes' section on the summary screen and press the 'Save' button for the notes.

5.7 Process the Report

5.7.1 Select the 'Process Report' button to save the report and lock the version. This also exports data, so it is available for integrated systems (i.e. when using an Enterprise software license).

5.8 Revisions to the Report

5.8.1 Making changes to a processed report requires the use of the 'Version Report' button. This creates a new revision of the same report that can then be edited. Navigate the software as before and then edit information or reread dosimeters. Process the report again upon completion of edits.

5.9 Printing / Exporting the Report





5.9.1 Create a PDF report or export data to MS Excel using the buttons on the upper-right of the Report Summary Screen. The PDF icon will create a PDF of the report; the Excel icon will export the report to MS Excel. See an example of report outputs in the table below:

[Below is an example only – replace with actual information for user site]

Report Name	Report Type	Electronic or Paper	Location
Routine Dosimetry	PDF	Paper	File drawer in Dose Lab
Dose Map	MS Excel	Electronic	D:\sharedfiles/dosimetry
Beam Energy Report	MS Excel	Paper and Electronic	File drawer in Dose Lab D:\sharedfiles/dosimetry

5.10 Storage of Irradiated Dosimeters

5.10.1 Dosimeters are stored in the lab for [user specified – i.e. 14 days] after irradiation and may only be remeasured during this time interval.

5.10.2 After the user specified time, (i.e. 14 days) the dosimeters and their packaging may be disposed of in general waste receptacles.

Disclaimer - The information contained in this document is provided “as is” and is not a substitute for the user’s professional judgement. It is provided as a convenience to those using products provided by GEX Corporation who have sufficient technical skills to evaluate and properly apply the information in this document. It is the responsibility of the user of this document to ensure that the information in this document, and the use of such information, is accurate, complete, applicable to the product, suitable for the user’s purposes, and in compliance with all laws and regulations. GEX Corporation believes the information provided in this document is accurate and reliable as of the time of writing, but it undertakes no obligation to update or correct this document. GEX Corporation may, but is not required to, make changes to this document at any time without notice. By using the information in this document, the user represents and warrants that he or she has the skills necessary to properly understand and apply this information and that he or she will comply with all applicable laws and regulations including, without limitation, those relating to medical devices, pharmaceutical products, or other applicable industries. The user assumes all risks associated with using this information and any results or output resulting from the application of this information to GEX Corporation’s products. The user agrees not to hold GEX Corporation liable for any errors or omissions contained within.

